VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 05/13/08

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Cheryl Gibson, M.D.
Norman Ward, M.D.
Kathleen Boland, Pharm.D.
Richard Harvie, R. Ph.
Lynne Vezina, R.Ph.
Stuart Graves, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Robin Farnsworth, OVHA
Nancy Miner, (MHP)
Stacey Baker, OVHA
Judy Jamieson, OVHA
Jennifer Mullikin, OVHA

Guests:

Amy Finn, Merck
Byon Yeatts, DK Pierce & Associates
Daniel Martin, Elan
Glenn E. Dooley, Sr, Sanofi-Aventis
Joseph Winalski, Biogen Idec
Julie Baker, TAP
Lyndon Braun, Santarus
Michael Deorsey, Abbott
Nancy Amerio, GSK
Paul Cernek, Elan
Paul Kelly, Janssen
Scott Mosher, GSK
Shannon Partenza, TAP
Susan Gretkowski, MMR
Terry Lalancette, GSK
Tracy Bernasconi, AstraZeneca
Tracy Wall, Merck

Michael Scovner, M.D. called the meeting to order at 7:05 p.m at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The April 2008 minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Annual completion of Disclosure Questionnaires: Completion of the annual disclosure questionnaires by DUR Board members is due in June. The questionnaire has been included in the May DUR Board packet.

- Department of Mental Health review of mental health classes/criteria: OVHA has been in contact with the Department of Mental Health for comment on VT Medicaid's mental health drug categories and criteria. To date, the Department has not made any recommendations.

4. Medical Director Update:

Clinical Programs Update: No updates to report. Medical Director absent.

Prescriber Comments: No comments to report**.**

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Pregnancy Categories for Ophthalmic Medications:
  The Board asked for an explanation of how pregnancy categories are assigned for ophthalmic preparations. A summary of pregnancy categories for ophthalmic products discussed at the previous meeting was presented. The pregnancy categories were assigned based on animal studies in which the concentration studied was significantly higher than what would be achieved with ophthalmic application.

Public Comment: No public comment.

Board Decision: None needed.

6. Clinical Update: Drug Reviews *Diane Neal, R.Ph.(MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Flector® (diclofenac epolamine 1.3%) Transdermal Patch: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being documentation of medical necessity for a transdermal formulation (ex. dysphagia, inability to take oral medications) or the patient has had a documented intolerance (gastrointestinal side effect) to two or more preferred NSAIDS (one of the trials must be with oral diclofenac), used in combination with either misoprostol or a proton pump inhibitor (PPI). A quantity limit of 2 patches per day was recommended.

Public Comment: No public comment.

Board Decision: The Board voted that gastrointestinal intolerance should not be included as a criterion for approval and unanimously agreed with the other recommendations.

- Iquix® (levofloxacin 1.5%) Ophthalmic Solution: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being the member has experienced an intolerance or inadequate response to ciprofloxacin 0.3% ophthalmic solution or ofloxacin 0.3% ophthalmic solution.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations as described. The Board requested that the table in the Clinical Criteria Manual be modified to indicate which products are preservative free and to change the approval length from date of service to duration of therapy requested.

- Lidoderm® (lidocaine 5%) Transdermal Patch: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the diagnosis or indication is neuropathic pain/post-herpetic neuralgia and the patient has had a documented side effect, allergy, treatment

failure or contraindication to TWO drugs in the tricyclic antidepressant (TCA) class and/or anticonvulsant class and the patient has had a documented side effect, allergy, treatment failure or contraindication to Lyrica® or the patient has a medical necessity for a transdermal formulation (ex. dysphagia, inability to take oral medications). In addition, a quantity limit of 3 patches/day is recommended.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations as described.

- Somatuline® (lanreotide) Depot Injection: An evaluation of Somatuline® was presented. A quantity limit of 0.2 ml/28 days (60 mg syringe), 0.3 ml/28 days (90 mg syringe), and 0.5 ml/28 days (120 mg syringe) is recommended in order to eliminate pharmacy billing errors. This category is currently unmanaged and it was recommended that the category continue as unmanaged.

Public Comment: No public comment.

Board Decision: The Board voted to manage Somatuline® to limit use to the approved indication of acromegaly. The drug will be listed as preferred after clinical criteria are met and these criteria will be applied whether the drug is claimed through either the medical or pharmacy benefit. The Board approved the MHP recommendations for quantity limits.

- Tysabri® (natalizumab) Intravenous Injection (in Crohn's & MS & FDA warning): Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval for **Crohn's Disease** to be the patient has a diagnosis of Crohn's disease and has already been stabilized on Tysabri® or the diagnosis is moderate to severe Crohn's disease and at least 2 of the following drug classes resulted in an adverse effect, allergic reaction, inadequate response, or treatment failure (i.e. resistant or intolerant to steroids or immunosuppressants): aminosalicylates, antibiotics, corticosteroids, and immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate and the patient has a documented side effect, allergy, treatment failure, or contraindication to BOTH Remicade® and Humira®. In addition, a quantity limit of 300 mg/28 days was recommended. The criteria for approval for **Multiple Sclerosis** to be the patient has a diagnosis of relapsing multiple sclerosis and has already been stabilized on Tysabri® or the diagnosis is relapsing multiple sclerosis and the patient has a documented side effect, allergy, treatment failure, or contraindication to at least two preferred drugs (e.g., Avonex®, Betaseron®, Rebif®, Copaxone®). In addition, a quantity limit of 300 mg/28 days was recommended. Theses criteria would be applied to use of Tysabri® in both the pharmacy and medical benefits.

Public Comment: *Paul Cernek, Elan* – Commented on the efficacy of Tysabri in Crohn's Disease.
Daniel Martin, Elan – Discussed use in Multiple Sclerosis in addition to use in Crohn's Disease.

Board Decision: The Board approved the MHP recommendations as described.

7. **Review of Newly-Developed/Revised Clinical Coverage Criteria:** *Diane Neal, R.Ph, (MHP)*
(Public comment prior to Board action)

Criteria Changes

- Miscellaneous: Soliris® (Paroxysmal Nocturnal Hemoglobinuria Injectable) – further definition of criteria:
The criteria were originally approved in September 2007 with solely a diagnosis of paroxysmal nocturnal hemoglobinuria. It was recommended that the criteria be expanded to be the patient has a diagnosis of paroxysmal nocturnal hemoglobinuria and the patient receives at least one red blood cell transfusion per month or 12 transfusions per year and the hemoglobin level is < 9g/dl (in patients with symptoms), or < 7g/dl (in patients without symptoms) and the patient has received the meningococcal vaccine and the request is for a quantity limit of 20 vials (of 300 mg/30 mL) total with initial approval duration of 3 months and a quantity limit of 6 vials per month with recertification approvals.

Public Comment: Byon Yeatts, DK Pierce & Associates Inquired whether the discussion could be postponed.

Board Decision: The Board approved the MHP recommendations as described.

- Pulmonary: Antihistamines: 2nd Generation (Allegra ® (fexofenadine) ODT (orally disintegrating tablet)):
Not recommended for addition to the PDL. The criteria for approval would be the diagnosis or indication for the requested medication is allergic rhinitis or chronic idiopathic urticaria and the patient has had a documented side effect, allergy, or treatment failure to loratadine (OTC) chewable/dissolvable tablets.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the recommendations as described.

- Humira® (new indications) and Remicade® (for indications other than Crohn's):
(a) Ankylosing Spondylitis Medications: Injectables – No changes recommended for this category.
(b) Gastrointestinals:Ulcerative Colitis Medications: Injectables – No changes recommended for this category.
(c) Psoriasis Medications: Injectables – Recommended that Humira® be added as preferred after clinical criteria are met. Approval criteria to be the prescription must be written by a dermatologist and the patient has a documented diagnosis of moderate to severe plaque psoriasis and has already been stabilized on Humira® or the prescription must be written by a dermatologist and the patient has a documented diagnosis of moderate to severe plaque psoriasis affecting > 10% of the body surface area (BSA) and/or has involvement of the palms, soles, head and neck, or genitalia and has had a documented side effect, allergy, inadequate treatment response, or treatment failure to at least 2 different categories of therapy [i.e. at least 2 topical agents and at least 1 oral systemic agent, (unless otherwise contraindicated)] from the following categories: Topical agents: emollients, keratolytics, corticosteroids, calcipotriene, tazarotene, etc.,Systemic agents: methotrexate, sulfasalazine, azathioprine, cyclosporine, tacrolimus, mycophenylate mofetil, etc. and Phototherapy: ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA, narrow band ultraviolet B (NUVA), etc.

(d) Rheumatoid & Psoriatic Arthritis Medications: Injectables – Recommended to rename category as Rheumatoid, Juvenile & Psoriatic Arthritis Medications: Injectables and to add juvenile idiopathic arthritis as an approvable indication for Humira® to the previously established clinical criteria.

No changes were recommended for any of the Remicade® criteria in the above four managed categories.

Public Comment: No public comment.

Board Decision: The Board approved the changes to the managed categories as indicated above and approved the annual review of Ankylosing Spondylitis Medications: Injectables and Gastrointestinals:Ulcerative Colitis Medications: Injectables as described.

8. New Drug Classes:

- Analgesics: Local Anesthetics:Transdermal:
  The proposed new category that will include Lidoderm® was presented. Length of authorization after approval is six months.

Public Comment: No public comment.

Board Decision: The new category with criteria as previously discussed was unanimously accepted.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Acetaminophen > 4 grams/day:
  As a follow-up to a previous retrodur presented in September 2007, pharmacy claims for acetaminophen-containing products with daily doses of > 4 g of acetaminophen during the 3-month time period after the quantity limit restriction was implemented (October 1, 2007 to December 31, 2007) were reviewed. In addition, all prior-authorization requests received by the clinical call-center for the agents listed above (due to the quantity limit restriction) were reviewed. From 10/1/07 to 12/31/07, there were 531 prescriptions for acetaminophen or a combination acetaminophen/opioid product containing > 4 grams of acetaminophen for 387 unique utilizers. There were no claims for the products that currently have quantity limits. It was recommended that quantity limits should be applied to all 26 additional products that were identified in the analysis to ensure that each product is limited to 4 grams of acetaminophen/day on a given claim. As a subsequent initiative, data should be collected to identify those patients who have received an average of > 4grams of acetaminophen/day as a result of 2 or more claims filled within a given time period and letters should be sent to these patient's prescribers to notify them of this occurrence. The clinical call-center received 3 requests for prior-authorization for these agents during this time period where the quantity exceeded acetaminophen 4 grams/day. One prescription was changed to a lower quantity and two requests were denied.

Public Comment: No public comment.

Board Decision: The Board requested that this topic be addressed in a future issue of the OVHA Pharmacy bulletin, particularly drawing attention to patients who may be taking multiple different acetaminophen containing products including over-the-counter products. The Board also supported the use of products that contain at most 325 mg of acetaminophen. Data will be brought to a later meeting that will summarize the number of claims that are for products containing more than 325 mg

acetaminophen. The Board approved the quantity limits for the 26 additional products as outlined. The Board also requested data on the number of liver transplants in the Medicaid program.

- Advair®:
  An Advair® drug utilization review for the 6 month period 08/01/2007 through 01/31/2008 was presented. During this time period there were 687 new starts (number of unique patients on Advair® without an Advair® prescription in the previous 6 months since their last fill) and of these 539 (78.5 %) did not have a pharmacy claim for an inhaled steroid or any other controller or COPD medication (leukotriene antagonists, mast cell stabilizers, inhaled anticholinergics) in the previous year. It appears that the combination product Advair® (corticosteroid/long acting beta agonist) is being prescribed first line before trials of any other controller medications. Additionally, of the 452 new starts between 08/01/07 and 10/31/07, 284 patients had no additional fills through 02/11/08 (that is the patient only had a single fill through at least an additional 4 months), 53 patients (18.66 %) had no history of any other asthma or COPD-related meds in their profile for more than a year (1/1/07 - 2/11/08) indicating that they are presumed to be non-asthmatic or non-COPD. The Advair® package insert lists important limitations as (1) Not indicated for patients whose asthma can be managed by inhaled corticosteroids with occasional use of inhaled short-acting beta2-agonists and (2) Not indicated for the relief of acute bronchospasm.

Public Comment: No public comment.

Board Decision: The Board requested that medical claims history be matched up with these claims to determine the diagnosis of the patients identified.

Cost Savings/Clinical Analysis of Prior Initiatives:

- Angiotensin Receptor Blocker Step Therapy Cost Savings:
  Beginning 02/15/2007, a step therapy was implemented for all new patients prescribed an angiotensin receptor blocker (ARB) or ARB combination anti-hypertensive. This step therapy requires a previous trial of an angiotensin converting enzyme inhibitor (ACEI) or ACEI combination anti-hypertensive. Patients who were currently a user of an ARB or ARB combination were grandfathered. An analysis of a 6 month period of claims history (11/07/07 – 05/06/08) which began 9 months after the change showed the percentage of new starts beginning with an ACEI or ACEI combination at 89.4 % and the percentage of ACEI/ACEI combination of total ACEI/ACEI combination/ARB/ARB combination increasing from 72.5 % to 75.74 % with a resultant annual savings of approximately $ 55,000.00

Public Comment: No public comment.

Board Decision: None needed.

10. New Drug Product Plan Exclusions: *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 04/10/08 - 05/08/08. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*
FDA Safety Alerts

- Singulair® (montelukast) – behavior/mood changes:
  The FDA informed healthcare professionals and patients of the Agency's investigation of the possible association between the use of Singulair® and behavior/mood changes, suicidality (suicidal thinking and behavior) and suicide. Healthcare professionals and caregivers should monitor patients taking Singulair® for suicidality (suicidal thinking and behavior) and changes in behavior and mood. Due to the complexity of the analyses, the FDA anticipates that it may take up to 9 months to complete the ongoing evaluations. It was recommended that no action is required on the part of the DUR Board and that the alert be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

- Neupro®: (rotigotine transdermal system) – crystals in patch:
  Schwarz Pharma informed healthcare professionals and patients of the recall of Neupro®, a transdermal delivery system worn on the skin and used to treat early stage Parkinson's disease, at the end of April 2008, because of the formation of rotigotine crystals in the patches. When the drug crystallizes, less drug is available to be absorbed through the skin and the efficacy of the product may vary. Healthcare professionals should not initiate any new patients on Neupro® and should begin to down-titrate all patients currently using the product per the guidelines in the product labeling. Patients should NOT abruptly discontinue therapy. Abrupt withdrawal of dopamine agonists has been associated with a syndrome resembling neuroleptic malignant syndrome or akinetic crises. The communication will be posted on the OVHA pharmacy web site.

Public Comment: No public comment

Board Decision: The Board approved the posting of the alert.

- Celcept® (mycophenolate mofetil)/Myfortic® (mycophenolate acid) – association with PML:
  The FDA informed healthcare professionals that the Agency is investigating a potential association between the use of CellCept® and Myfortic®, medicines used to prevent organ rejection, and the development of progressive multifocal leukoencephalopathy (PML), a life-threatening disease. The FDA anticipates it may take about 2 months to complete its review of the postmarketing reports and the proposed revisions to the prescribing information The recommendation is that no action is

required on the part of the DUR Board in response to this communication. The communication will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

- Digitek® (digoxin tablets) – Class I recall – fax blast to pharmacies:
  Actavis Totowa LLC notified healthcare professionals of a Class I nationwide recall of all strengths of Digitek®, a drug used to treat heart failure and abnormal heart rhythms. The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label. The product is being recalled due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of digitalis toxicity. A Fax Blast sent to pharmacies by MedMetrics/OVHA was shared with the Board.

Public Comment: No public comment.

Board Decision: None required.

13. Adjourn: Meeting adjourned at 9:20 p.m.

Next DUR Board Meeting
Tuesday, June10, 2008
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.